

## REMARKS

### Claim Rejections – 35 U.S.C. 102 (b)

Claims 1, 3, 5-11, 13-18, 23, 26-32, 36 and 38 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,373,859 to Forney. Applicant respectfully traverses these rejections for the reasons now following.

Dealing first with claims 1, 3 and 5, independent claim 1 is directed towards one embodiment of the present invention, namely, a tongue retention device comprising a single flange and a protrusion whereby the flange and protrusion comprise an integrally molded one-piece body.

The Examiner states that Forney discloses at column 4, lines 25-29, a single flange and protrusion that are an integrally molded one-piece body. This is not the case. Column 4, lines 25-29 states that the seal opening 30, the housing 10 and the vacuum reservoir 20 are all molded or formed to make an integral, one-piece device in accordance with the invention. However, Forney does not teach an integral, one-piece device that further comprises flange 40.

Forney states at column 4, starting at line 54 that "[i]n certain embodiments, the housing 10, seal opening 30 and vacuum reservoir 20 alone will create a useful device that can be used to hold and manipulate the tongue". However, addition of a flange 40 is a preferred embodiment (see column 4, lines 66-68), and "[t]he flange 40 is attached to the exterior of the housing 10" [emphasis added]. In all embodiments, the flange is formed separately from the housing and then later attached to the housing.

Thus, Forney does not teach a flange and a protrusion (*i.e.* tongue housing) that comprise an integrally molded one-piece body. In fact, Forney teaches away from such an element. In particular, Forney states at paragraph 5, lines 16-17 that "[t]he flange 40 is preferably molded from a thin sheet of material" or, in the alternative, that "[t]he flange 40...is a simple collar 40 prime cut from a flat plate of rigid material". Clearly, Forney anticipates forming the flange separately from the rest of the tongue retention device.

Thus, in the instant case the flange and protrusion do not have to be pressed fitted or glued together because these two components are in fact a single, one-piece body formed by a molding-like manufacturing procedure. Hence, the tongue retention device is manufactured from a single mold using a single material, hence, ensuring uniformity of material throughout the entire device.

There are definite commercial advantages in having a tongue retention device designed as a one-piece molded body. For example, such a device would likely be easier and cheaper to make than those tongue retention devices which have several elements that need to be manufactured separately and then "pieced" together. As well, the manufacturing time would likely be much less for a one-piece device. Finally, quality control would be much easier.

It is respectfully submitted that there is nothing in Forney to suggest that the flange and protrusion/housing comprise an integrally molded one-piece body. As the Forney reference does not teach all of the elements of claim 1, it is respectfully submitted that claim 1 and dependent claims 3 and 5 are not anticipated by this prior reference.

Turning now to claims 7, 8, 9 and 10, Applicant's independent claim 7 recites a tongue retention device comprising a single flange, the flange being sized and shaped to be received between a person's lips and frontal surface of a person's teeth or alveolar ridges if teeth are absent, and a tongue housing, *i.e.* bulb, wherein the bulb has an aperture for receiving the tongue and the proximal end of the aperture is contiguous with the flange.

As can be seen most clearly in Figure 1 of the present application, the only element of the device that extends from the flange is bulb 18, which extends from the distal end of the aperture and the first surface of the flange. Hence, the proximal end of the device as a whole is the flange itself as the bulb only extends from the distal end of the aperture (and first surface of flange). Hence, no part of the tongue retention device of the present invention extends proximally from the flange. Thus, when the flange is properly positioned in a user's mouth between the user's lips and frontal surface of the user's teeth, there is no part of the device that extends into the user's oral cavity. The fact that the present tongue retention device does not protrude into the oral cavity is one of the advantages of the present device over other devices (see, for example, page 10, lines 18-20).

In Forney, however, the proximal end of flexible seal opening 30, which is disposed at the proximal end of the housing 10 and is comparable to Applicant's aperture, is not contiguous with the flange 40. In fact, housing 10 (and hence flexible seal opening 30) extends well beyond the proximal end of flange 40 such that the proximal end of flange 40 is not the most proximal element of the Forney device. This can most clearly be seen in Figure 5, where the proximal end of housing 10 clearly extends past the proximal end of flange 40. This structural difference can be seen in all embodiments of the Forney device, *i.e.* in Figures 1, 2, 3 and 6.

Furthermore, Forney does not disclose a single flange that can be positioned between the lips and the frontal surface of the user's teeth, as suggested by the Examiner. In fact, column 5, lines 40-41, states that "flange 40 rests against the face of the subject, *i.e.*, against the lips, teeth and/or surrounding tissue" [emphasis added]. Forney also states in column 5, lines 37-40 "the flange is most preferably sized to extend from beneath the patient's nose to the chin area, thereby partially covering the mouth" [emphasis added]. It is also clear from viewing Figures 4 and 5 that the flange of the Forney device is intended to rest against the face of the subject. In particular, Figure 5 clearly shows flange 40 as being in front of the user's lips. In the present invention, the flange never covers the mouth nor does it ever rest against a user's face, as the flange is sized and shaped for insertion between the lips and teeth of the user.

As the Forney reference does not teach all of the elements of claim 7, it is respectfully submitted that claim 7 and dependent claims 8, 9 and 10 are not anticipated by this prior reference.

Turning to claims 13 –16, independent claim 13 is directed towards a method of retaining a tongue in a predetermined position comprising, among other steps, positioning said flange between a user's lips and frontal surface of said user's teeth. As can be clearly seen in both Figures 4 and 5 of Forney, and from reading the specification, as discussed above the flange of the Forney device is positioned against a subject's face. Thus, Forney does not teach a method for retaining a tongue in a predetermined position that includes the step of positioning the flange between a user's lips and frontal surface of said user's teeth.

As the Forney reference does not teach all of the elements of claim 13, it is respectfully submitted that claim 13 and dependent claims 14-16 are not anticipated by this prior reference.

With reference now to claims 17, 18, 23, and 26-31, independent claim 17 is directed towards a tongue retention device comprising a bulb having a closed and open end and a single flange that extends outwardly from the open end, wherein single flange being sized and shaped to be received between a person's lips and frontal surface of said person's teeth.

Forney does not teach a single flange that extends outwardly from the open end. In the Forney device, flange 40 does not extend outwardly from the open end of the housing 10, *i.e.* flexible seal opening 30. This can be clearly be seen in Figures 1, 2, 3, 5 and 6 of Forney. As a result of the present invention having a flange that extends outwardly from the open end of the tongue housing (bulb), no element of the present device extends proximally from the flange. This is not the case with the Forney device (once again, refer to Forney Figures 1, 2, 3 and 6).

Hence, when the flange of the present invention is properly positioned in a user's mouth between the user's lips and frontal surface of the user's teeth, no part of the present device extends into the user's oral cavity. As previously mentioned, the fact that the present tongue retention device does not protrude into the oral cavity is listed as one of the advantages of the present device over other devices (see, for example, page 10, lines 18-20).

Furthermore, Forney does not teach a single flange being sized and shaped to be received between a person's lips and frontal surface of said person's teeth. As stated in Forney at column 5, lines 40-41, "flange 40 rests against the face of the subject, *i.e.*, against the lips, teeth and/or surrounding tissue" [emphasis added]. Forney also states in column 5, lines 37-40 "the flange is most preferably sized to extend from beneath the patient's nose to the chin area, thereby partially covering the mouth" [emphasis added]. It is also clear from viewing Figures 4 and 5 that the flange of the Forney device is intended to rest against the face of the subject.

As the Forney reference does not teach all of the elements of claim 17, it is respectfully submitted that claim 17 and dependent claims 18, 23, and 26-31 are not anticipated by this prior reference.

With reference now to claims 32, 36 and 37, independent claim 32 is directed towards a tongue retention device comprising a single flange, an aperture and a protrusion forming a hollow chamber, wherein the single flange is sized and shaped to be comfortably received between a person's lips and frontal surface of a person's teeth or alveolar ridges if teeth are absent.

The Forney reference does not teach a flange which is sized and shaped to be comfortably received between a person's lips and frontal surface of a person's teeth or alveolar ridges if teeth are absent. Instead, the Forney flange 40 is sized and shaped to "rest against the face of the subject, *i.e.*, against the lips, teeth and/or surrounding tissue" (see column 5, lines 40-42). Further, Forney states at column 5, lines 37-40 that "the flange is most preferably sized to extend from beneath the patient's nose to the chin area, thereby partially covering the mouth" [emphasis added].

It is clear that Forney does not teach nor even suggest a flange that is sized and shaped to be received between the lips and teeth. In fact, Forney teaches away from such a flange as it would likely be impossible to comfortably insert a flange as described at column 5, lines 37-40, between a person's lips and teeth. Hence, it is respectfully submitted that Forney does not teach a flange that is sized and shaped to be comfortably received between a person's lips and frontal surface of a person's teeth or alveolar ridges if teeth are absent.

As the Forney reference does not teach all of the elements of claim 32, it is respectfully submitted that claim 32 and dependent claims 36 and 37 are not anticipated by this prior reference.

#### **Claim Rejections – 35 U.S.C. 103(a)**

Claims 2, 4, 12, 19-21, 25, 33-35, 37, 39 and 44-45 were rejected under 35 U.S.C. 103(a) as being obvious in view of Forney and U.S. Patent No. 5,465,734 to Alvarez. Applicant respectfully traverses these rejections for the reasons now following.

Claims 2 and 4 are dependent on claim 1, which recites a tongue retention device comprising a flange and a protrusion, whereby the flange and protrusion comprise an integrally molded one-piece body. Forney does not teach a device where the flange and protrusion comprise an integrally molded one-piece body (see above discussion). Thus, Forney does not "disclose in figures 1-2 a device for retaining a tongue, substantially as claimed". Neither does Forney suggest such a device. Thus, it would not be obvious to the skilled artisan to make a tongue retention device as claimed in claims 2 and 4 in view of Forney and Alvarez.

Claim 12 is dependant upon claim 8, which in turn is dependant upon claim 7. Thus, claim 12 recites a tongue retention device comprising a flange having an aperture and a bulb

wherein the proximal end of the aperture is contiguous with the flange. Further, the flange is sized and shaped to be comfortably received between a person's lips and frontal surface of a person's teeth or alveolar ridges if teeth are absent. As previously mentioned, Forney does not teach a device where the aperture is contiguous with the flange. Furthermore, Forney does not teach a flange that is sized and shaped to be comfortably received between a person's lips and frontal surface of a person's teeth or alveolar ridges if teeth are absent. Thus, Forney does not "disclose in figures 1-2 a device for retaining a tongue, substantially as claimed". Neither are these elements suggested in Forney. Thus, it would not be obvious to the skilled artisan to make a tongue retention device as claimed in claim 12 in view of Forney and Alvarez.

Claims 19-21 and 25 are dependent on claim 17, which recites a tongue retention device comprising a bulb having a closed and open end and a single flange that extends outwardly from the open end, wherein single flange being sized and shaped to be received between a person's lips and frontal surface of said person's teeth. As previously mentioned, Forney does not teach a single flange that extends outwardly from the open end, wherein single flange being sized and shaped to be received between a person's lips and frontal surface of said person's teeth. Thus, Forney does not "disclose in figures 1-2 a device for retaining a tongue, substantially as claimed". It would not be obvious to the skilled artisan to make a tongue retention device as claimed in claims 19-21 and 25 in view of Forney and Alvarez.

Claims 33-35, 37 and 39 are dependent on claim 32, which recites a tongue retention device comprising a single flange, an aperture and a protrusion forming a hollow chamber, wherein the single flange is sized and shaped to be comfortably received between a person's lips and frontal surface of a person's teeth or alveolar ridges if teeth are absent. As previously mentioned, Forney does not teach a single flange being sized and shaped to be received between a person's lips and frontal surface of said person's teeth. Thus, Forney does not "disclose in figures 1-2 a device for retaining a tongue, substantially as claimed". It would not be obvious to the skilled artisan to make a tongue retention device as claimed in claims 33-35, 37 and 39 in view of Forney and Alvarez.

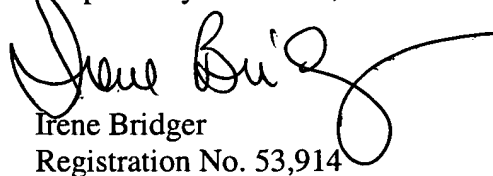
With respect to claims 44 and 45, independent claim 44 claims a kit comprising a tongue retention device comprising a bulb having a closed and open end and a single flange that extends outwardly from the open end.

As previously mentioned, Forney does not teach a single flange that extends outwardly from the open end. In the Forney device, flange 40 does not extend outwardly from the open end of the housing 10, *i.e.* flexible seal opening 30. This can be clearly be seen in Figures 1, 2, 3, 5 and 6 of Forney. As a result of the present invention having a flange that extends outwardly from the open end of the tongue housing (bulb), no element of the present device extends proximally from the flange. This is not the case with the Forney device (once again, refer to Forney Figures 1, 2, 3 and 6). Thus, Forney does not "disclose in figures 1-2 a device for retaining a tongue, substantially as claimed".

Furthermore, neither Forney nor Alvarez suggests a flange which overall size can be adjusted to fit comfortably between a person's lips and teeth. Thus, neither Forney nor Alvarez discloses a kit comprising instructions comprising adjusting the overall size of the flange to comfortably fit between a person's lips and teeth. Hence, it would not be obvious to the skilled artisan to make a kit as claimed in claims 44 and 45 in view of Forney and Alvarez.

In view of the arguments presented by Applicant herein, Applicant submits that claims 1-5, 7-10, 12, 15-39, 44 and 45 are in a condition for allowance and such allowance is respectfully requested.

Respectfully submitted,

  
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